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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,813	10/05/2001	Nicholas W. Warne	22058-531CON (GI-5371)	3576

7590 08/25/2004

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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/971,813	WARNE ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-25 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The use of the trademark TWEEN, e.g., TWEEN 20, has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

2. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 is indefinite as it recites a product identified by its trademark (TWEEN 20). Given that a product so identified is subject to change without public notice, the metes and bounds of the product so identified and to which the claims are to be limited is unclear.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time that any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,371,193 (Bennett et al.), US Patent 5,679,339 (Keith et al.), and US Patent 6,09,873 (Schaefer et al.).

8. Bennett et al., disclose and claim (claim 4) a pharmaceutical composition comprising IL-II. Column 9 states in part that "[t]he preparation of such a pharmaceutically acceptable protein solution, having due regard to pH, isotonicity, stability and the like, is within the skill of the art.

9. Bennett does not set forth in specific detail the concentrations and additives specifically identified in the now claimed composition.

10. Keith et al., at columns 7 and 8, disclose various compositions of IL-II. As seen therein, the compositions may comprise polyethylene glycol, single amino acids such as glycine or histidine, sucrose, and various concentrations. At column 8, fifth paragraph, the preparation of a lyophilized composition of IL-II is disclosed; a limitation of claim 25.

11. Keith et al., do not disclose the inclusion of methionine or TWEEN 20 in the composition.

12. Schaefer et al., disclose a multitude of commonly accepted pharmaceutical formulations. While the disclosure is directed to gamma-heregulin, a polypeptide that stimulates the growth of cells, such disclosure is directly applicable to the formulations of IL-II as both heregulin and IL-II are proteins that act upon cells. At column 27, last paragraph, bridging to column 28, first paragraph, there is disclosed the concept of including in a pharmaceutical composition low molecular weight proteins that are further characterized as having less than 10 amino acids. Such renders obvious the inclusion of the antioxidant L-methionine (a limitation of claims 11-14, 23, and 24) as well as glycine (a limitation of claims 1-29). In column 28, the inclusion of disaccharides renders obvious the inclusion of the cryoprotectant sucrose; a limitation of claims 1-29. The inclusion of surfactants generally, renders obvious the inclusion of polysorbate, a limitation of claims 7-10, 22, and 23. Schaefer et al., also teach specifically of including any of the surfactants sold under the trademark of TWEEN (column 28); this meets a limitation of claim 8.

13. In view of the totality of the teachings in the art as to the preparation of any number of formulations of polypeptide-containing compositions which act upon a cellular

process, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have expanded upon the "pharmaceutical composition" taught by Bennett et al., so to include the added reagents and formulations disclosed by both Keith et al., and Schaefer et al.

14. In view of the profound medical significance imparted to IL-II, the ordinary artisan would have been highly motivated to prepare such pharmaceutical compositions and in view of the well-developed nature of this part of the pharmaceutical art, said ordinary artisan would have had a reasonable expectation of success. For the above reasons and in the absence of convincing evidence to the contrary, the claimed invention is considered to be obvious in view of the prior art of record.

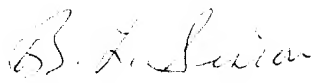
Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
23 August 2004